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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,824	06/30/2003	John J. Allen	LIFE-096CON4	2999
24353	7590	05/03/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303				MENON, KRISHNAN S
		ART UNIT		PAPER NUMBER
		1723		

DATE MAILED: 05/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/611,824	ALLEN ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Krishnan S. Menon	1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 April 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 9-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 9, 15-20, 25 and 26 is/are rejected.
- 7) Claim(s) 10-14, 21-24 and 27 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date _____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

Claims 9-27 are pending.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 20 and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by European Patent Application No. 0 396 016 A2 (hereinafter referred to as EP :016).

EP'016 teaches an apparatus for collecting body fluid for testing an analyte in body fluid, such as blood, comprising a conduit (308) having a first end for admitting a body fluid and transporting body fluid to a discharge end of the conduit, a planar test body (402) having a first surface and a second surface and a hub extending from the first surface and comprising a bore extending through the first surface wherein the discharge end of the conduit (308) is positioned coaxially within the bore wherein a reservoir is defined by the space within the bore not occupied by the discharge end of the conduit (308) (see figures 23, 26) page 13, line 50 - page 15, line 34) (claim 20).

Regarding claim 25, test chamber (conduit 422) is aligned with sensors (244) including ion-selective electrodes, conductance, fiber optic or amperometric sensors for testing fluid for analyte (see figure 3, 12-18b, 27-284 page 7, lines 16-52,. page 15, line 44 - page 16, line 16).

Regarding claim 26, a hub (404) extends perpendicular to the planar body (400).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 9 and 15- 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP (016) in view of WO 97/38 126 (hereinafter referred to as WO t 126).

EP (016 teaches an apparatus for collecting body fluid for testing an analyte in body fluid, such as blood, comprising a conduit (16) having a first end for admitting a body fluid and transporting body fluid to a discharge end of the conduit, a reservoir for receiving and collecting a flow of body fluid from the discharge end of the conduit, a test adsorbent material and a test space (200) positioned substantially perpendicularly to the conduit (see the partial cross-section in fig 14 – cross-section of 200 is perpendicular to the needle 16) and between the test adsorbent material and the reservoir to be in contact with the fluid wherein the fluid in test space is drawn into a test chamber (202) with the test adsorbent material via capillaries (206) (see figures 13-14; page 11, lines 6-52).

Claim 9 essentially differs from the apparatus of EP :016 in reciting test membrane instead of test adsorbent material. WO (126) teaches a device for determining an analyte in blood wherein membranes from two categories are used as

follows: the first type is polyethersulfone polymeric membranes which are formed with a skin side which acts as a red cell barrier and a matrix side which has uniform pore size for containing indicator reagents and the second type includes cellulose glass fiber composites or polymer based matrix products which facilitate wicking of fluid and provide separation of blood solids from blood fluids (see page 15, line 1 - page 16, line 26. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute membrane for adsorbent matrix in the apparatus of EP :016 to separate out blood solids from blood liquids to measure analytes as suggested by WO (126).

Regarding claims 15-18, EP (016) teaches that ion-selective electrodes, conductance, fiber optic or amperometric sensors are aligned with the test adsorbent material for testing fluid for analyte (see figure 3, 12-18b; page 7, lines 16-524 page 11, line 6 - page 13, line 6).

Regarding claim 19, EP '016 suggest the use of vent (98) communicating with test chamber (80) through a capillary path (100) to allow air to escape from the sample chamber (86) as it is being filled with blood sample (see figure 6., page 8, lines 26-29).

### ***Allowable Subject Matter***

Claims 10-14, 21-24 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed 4/11/05 have been fully considered but they are not persuasive.

Argument re claims 20, 25 and 26: Relation of conduit (308), needle, with respect to the apparatus 400: claim only recites a conduit for admitting body fluid, and does not recite a structural link for the conduit (308) with the apparatus 400. Body 422 is planar with respect to the hub (404). Conduit 422 is a flat planar conduit under which the sensors 244 are located. For the disclosure for claims 25 and 26, please see the rejection.

Arguments re claim 9: 200 is a test space in that it has an absorbent (in chamber 202) in it, which is in communication with the sensors. Test space 200 is substantially perpendicular to the conduit (as explained in the rejection), it is between the test membrane (in this case, test absorbent in 202) and the reservoir, and the test space (through capillaries 206) wicks the fluid to the absorbent. There is nothing in the reference to construe that the absorbent in 202 is soaked before the fluid gets in to the reservoir.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Krishnan S. Menon  
Patent Examiner  
4/25/05

  
W. L. WALKER  
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